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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,531	12/14/2001	Sukhendu B. Dev	GENE1180-2	1163

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,531	DEV ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-9,17-20,23,24,29,30 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 7-9, 17-20, 23-24, 29, 30 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-9 and 17-20 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Leone et al., 5,505,700.

As to claim 1, Leone et al. discloses an apparatus comprising:

a catheter (11) having at least one inflatable balloon portion (16 and 17);

at least one infusion opening (19) for introducing the composition into a vessel;

a first electrode (35, see figure 1 and 2) on the catheter surface positioned adjacent to at least one infusion opening ;

and a second electrode (36) on the catheter surface positioned such that the infusion opening is disposed between the first electrode and the second electrode, wherein the second electrode is spaced a distance that allows an electric filed to be generated when a voltage is applied between the first and second electrodes after the catheter has been inserted into the vessel, wherein the electric filed is sufficient in strength to electroporate cells in the vessel, see column 4, lines 49-63, and column 7, lines 41-44.

With respect to claims 2, 11, 18, an electrical source is connected to the first and second electrodes for applying a voltage between the electrodes, see column 4, line 61.

With respect to Claims 3, 12 and 19, the vessel is a blood vessel (22).

As to claims 4, 13 and 20, the first electrode (35) is formed at least in part by a biologically inert material, see column 4, lines 56-57.

As to claim 14, the second electrode is a guidewire in the catheter, see column 4, line 63.

As to claim 7, the catheter has two inflatable balloon portions (16 and 17).

As to claim 8, the at least one infusion opening (19) is between the two inflatable balloon portions (16 and 17), see Figure 2.

As to claim 9, the first electrode (35) is coincident with the at least one infusion opening (19).

As to claim 17, Leone et al. discloses an apparatus comprising:

at least one inflatable balloon portion (17) at a position other than the distal end of the catheter;

proximal to the at least one inflatable balloon portion, an infusion opening (19) for introducing a composition;

a first electrode (35) on the catheter surface positioned adjacent to or integral with the infusion opening;

and a second electrode on the catheter surface (36, near balloon 16) (see fig. 1 and 2) on the catheter positioned proximal to but spaced from the first electrode a distance that allows an electric field to be generated when a voltage is applied between

the first and second electrodes after the catheter has been inserted into the vessel, wherein both the first and second electrodes are located proximal to the at least one balloon portion and the electric filed is sufficient in strength to electroporate cells in the vessel, see column 4, lines 49-63, and column 7, lines 41-44.

As to claim 18, an electrical source (15) is connected to the first and second electrodes for applying a voltage between the electrodes in an amount sufficient to cause electroporation of at least one cell.

As to claim 23, the first and second electrode is separately selected to be a single electrode or multiple electrodes, see column 4, lines 57-59.

As to claim 24, the multiple electrodes are interdigitated electrodes or concentric ring electrodes, see column 4, lines 63-67.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29, 30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leone et al., 5,505,700.

Leone et al. teach the invention substantially as claimed, see above. However, Leone et al. does not specifically disclose that the first and second electrodes are

suitable to receive an electric pulse having an electroporating voltage in the range as claimed, or wherein the electric field strength is in the range as claimed.

Leone et al. however does teach that the invention can be used for iontophoresis or electroporation, see column 7, lines 39-44. It would have been obvious to vary the Leone et al. device such that the device is capable of receiving an electric pulse having an electroporating voltage or electric field strength as specifically claimed, as necessary for achieving iontophoresis or electroporation. Also, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed March 28, 2005 have been fully considered but they are not persuasive.

Applicant argues on pages 5 through 7 that electrode (35) on the Leone device is not on the surface of the catheter. Applicant states that Leone refers to electrode (35) as the internal electrode, and that although the Leone reference is unclear as to the position of the internal electrode, the reference's disclosure is consistent with the interpretation that an internal electrode means that it is internal to the catheter.

Examiner disagrees with this interpretation. Examiner agrees that Leone does not specifically define what "internal" means. However, the disclosure of Leone supports the interpretation that the designation of "internal" means that it is comparable to the internal electrode in the prior art.

Leone states that the external or return electrode as used in the prior art devices wherein the external or return electrode is outside the patient is eliminated (col. 2, lines 18-23), and thus the undesirable aspects of having to pass electrical current through body tissue is eliminated (col. 2, lines 20-21.) Instead, the invention relies on the internal electrode and another electrode, the integral electrode (col. 2, lines 24-26, and col. 4, line 59), which is also on the catheter as opposed to being outside a patient's body.

In short, the fact that Leone uses the term "internal" electrode does not necessarily mean that the electrode is internal to the catheter. Rather, the specification supports that the designation "internal" is in keeping with the prior art designation of one electrode being called the internal electrode, i.e., the electrode that drives away the oppositely charged ionic medicament, as distinct from the other electrode, the external electrode outside the patient's body in the prior art. In other words, Leone's designation of electrode (35) as the internal electrode is simply a designation of the electrode to distinguish it from the other electrode (36), i.e., the integral electrode. This interpretation is consistent with the drawings of the embodiment in figures 1 and 2 which show electrode (35) on the outside of the catheter.

Applicant also argues on page 6 that Leone at column 6, lines 27-28, refers to the integral electrode 66 in Figure 4 as "external", which by inference precludes the internal electrode from being on the catheter exterior. In response, Examiner notes that Leone at column 6, lines 27-28, discloses: "Integral or external electrodes 66 are outside of balloon 61." The disclosure only states that the electrode 66 is outside of the

balloon. There is nothing in this disclosure that precludes the internal electrode from being on the catheter exterior.

Applicant also asserts on pages 6 to 7 that the shaded region on the catheter to show the catheter treatment length (34) means that the interior of the catheter is being shown and therefore electrode (35) is on the interior of the catheter. Applicant asserts that the shaded rendition of the catheter treatment length (34) does not represent porous or osmotic passageways because Leone makes it clear that the catheter contains either ports (19) or pores or osmotic passageways.

Examiner disagrees because Leone's description in column 4, lines 51-53 states that "medicament is infused either out of port(s) 19 or through pores or osmotic passageways of catheter treatment length 34". This disclosure does not mean that the catheter has either ports or pores or osmotic passageways, but not a combination. The statement and figure 2 clearly shows that the catheter has port(s) 19 and pores or osmotic passageways in (of) the catheter treatment length 34. The disclosure only states that fluid can go out of any of these various openings. Moreover, the shaded region of the catheter treatment length (34) in figure 2 for example is a means to indicate what portion of the catheter is the catheter treatment length (34), rather than to indicate that the inside of the catheter is being shown. In short, that the fact that the catheter treatment length (34) is shown to be shaded does not mean that the shaded region designates that the interior of the catheter is being shown and therefore electrode (35) is on the interior of the catheter, as argued by Applicant.

Applicant on page 7 states that it is not understood why the Office interprets the shading in Figure 2 as depicting treatment length 34. Examiner emphasizes that column 4, lines 53-54, explicitly and clearly states "catheteter treatment length 34".

Applicant also argues in the last paragraph on page 7 that "[b]ecause the cited patent and accepted meanings in the art make it clear that iontophoresis and electroosmosis involve movement of molecules across a semi-permeable barrier, Figure 2 of the '700 patent should be interpreted as disclosing the interior surface of the catheter treatment length 34 without the requisite semi-permeable barrier." Applicant's argument is not persuasive because Leone clearly indicates that catheter treatment length 34 has pores or osmotic passageways (col. 4, lines 53-54.)

Applicant states on page 7 that Applicants do not see a reason why Leone would shade treatment length 34 since other components of the catheter, such as the electrode 35, are readily visualized without shading. Examiner reiterates that element (34) is referred to as "catheter treatment length" and it is described as having "pores or osmotic passageways" (col. 4, lines 53-54 and see fig. 2.) This disclosure is consistent with figure 3, wherein element (44) is shaded in the same manner as element (34) in figure 2. Element (44) is described as "a porous membrane which covers internal electrode 45" (col. 5, lines 41-42.) Internal electrode (45) is in turn disclosed as being positioned on the outside of the catheter tube (52), (see figure 3). Thus, the shaded regions in figure 2 and figure 3 are both described as having pores, as opposed to the rest of catheter tube (52), which does not have pores. The shaded region does not, as Applicant insists, indicate that the interior of the catheter is being shown. (Examiner

notes that in figure 2, the shaded region, i.e., catheter treatment length with pores, is underneath electrode (35), and that in any case, electrodes (35) and (45) are both outside of catheter tube as shown in the figures 2 and 3.)

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

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06/10/05